



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/900,355 | 07/06/2001 | H. Craig Dees | PHO-122 | 5998 |

7590

02/18/2004

COOK, ALEX, McFARRON, MANZO,
CUMMINGS & MEHLER, LTD.
Suite 2850
200 West Adams St.
Chicago, IL 60606

EXAMINER

EPPS FORD, JANET L

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/900,355

Applicant(s)

DEES ET AL.

Examiner

Janet L. Epps-Ford, Ph.D.

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 November 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 19-27, 31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 19-27, 31 and 33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 12-08-03
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/24/03 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Response to Amendment

3. On page 7 of Applicant's response filed 11-14-03 Applicants state that Claims 28-20 are cancelled, this is believed to be an error, it is assumed that Applicants intended to state that Claims 28-30 were cancelled.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-4, 7-8, 10-11, 19-22, 25-27, 31, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Williams et al.

Williams et al. (US Patent NO. 5,576,013) teach the use of photodynamic therapy as an alternative to traditional chemotherapy and surgical treatments (see col. 1, lines 13-18). The methods of Williams et al. comprise applying a photosensitizing agent to target tissue consisting essentially of tissues containing blood-carrying vessels supply an undesired lesion, the agent being in a pharmaceutically acceptable composition, and illuminating an area consisting essentially of the treated blood-carrying vessels with light from a laser emitting light of a frequency and energy which excites the photosensitising agent and coagulates blood in said vessels (see col. 3, lines 20-31). Lesions and abnormal collections of unwanted vascular tissue that can be treated by the methods of Williams et al. include (*inter alia*) tumours (see col. 4, lines 65-67). The photosensitising agents that are useful in the methods of Williams et al. are those that will render blood in target tissues sensitive to coagulation from exposure to light. Exemplary agents include (*inter alia*) Rose Bengal (see col. 5, lines 5-14). The photosensitising agents of Williams et al. are brought into contact with the vascular tissue in target lesions by topical application or direct injection into the target tissue, and are administered in formulations, suitable formulations will be in combination with penetrating solvents or be in the form of a gel, lotion, cream, or ointment containing a sufficient amount of the light sensitizing agent (col. 5, lines 33-52). Topical formulations contain a sufficient amount of the photosensitising compound to be effective in photodynamic therapy. Generally, concentrations in the range of 0.001 to 25 wt. %, preferably from about 1 to 5 wt. %, may be used (see col. 7, lines 7-11).

Response to Arguments

6. Claims 1, 3-8, 19, 21-26, and 31-33 remain rejected under 35 U.S.C. 102(b) as being anticipated by Goers et al. Claims 1-11, 19-27, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Bottiroli et al. Claims 1, 3-6, 19, 21-24, and 31-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Schultz et al. Claims 2 and 20 are rejected under 35 U.S.C. 103(a) as being obvious over Goers et al. for the reasons of record set forth in the Official Action mailed 7-07-2003.

Applicant's arguments filed 11-14-2003 have been fully considered but they are not persuasive. Applicants traverse the above rejections on the grounds that the terms "chemotherapeutic" and "therapeutic" are not intended use limitations but are actual limitations of the claim. According to Applicants these terms breath life and meaning into the claim and therefore, recognized under well established law as a limitation of the claim. Moreover, Applicants argue that none of the cited references disclose or suggest this limitation of the claims, hence claim 1 and those claims dependent thereon are patentable over the cited references.

Contrary to Applicant's assertions, Applicants have not provided any evidence that the compounds disclosed by Goers et al. would not possess the same activity as the claimed compositions since the Goers et al. clearly state that photosensitizers, including in particular Rose Bengal (col. 20, lines 50-55), is disclosed as being a therapeutic agent. The photosensitizer is activated by a light source and its cytotoxic effect is mediated through the production of singlet oxygen, which results in toxicity to neighboring cells (col. 28, lines 45-68), this effect is not as a result of targeting moiety attachment. Moreover, the photosensitizer compositions of Goers et al. are disclosed as being specific

Art Unit: 1635

for tumor treatment (see col. 6, lines 22-28), and therefore can be considered a form of chemotherapeutic agent.

Moreover, as stated in the prior Office Action, Bottiroli et al. teach that the fluorogenic substrates can be administered for the treatment of tumors, i.e. as a medicament or pharmaceutical composition, comprising a dose varying from 1-to 10 mg/kg b.w. (i.e. halogenated xanthene is present in a concentration greater than about 0.0001% to less than about 20%), and administration can be systemic in the form of an isotonic saline solution, or as a suspension liposomes. Therefore, since Bottiroli et al. teach that halogenated xanthene containing pharmaceutical compositions can be used for the treatment of tumor, these compositions can also be considered a form of chemotherapeutic agent.

Schultz et al. disclose compositions comprising as a primary active functionality, a wide variety of fluoresces that may be employed either by themselves or in conjunction with quencher molecules as active functionalities. In one particular embodiment, the fluorescers include xanthene (col. 9, line 66), and more specifically may include Rose Bengal (col. 10, line 26). Applicant's arguments cannot take the place of evidence that the compositions disclosed by the cited references, particularly wherein the compositions comprise a halogenated xanthene, would not have the same functional activity as Applicant's claimed compositions. Applicants have not provided any evidence of structural dissimilarity between the compositions set forth in Goers et al., Bottiroli et al., or Schultz et al., therefore absent evidence to the contrary the ordinary skilled artisan would expect that the compositions disclosed in the cited references would have the same function as Applicant's compositions.

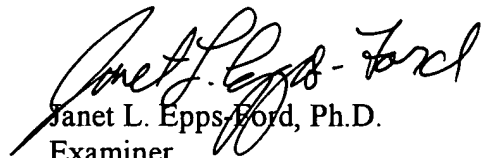
Art Unit: 1635

Applicant's arguments are not persuasive, the instant claims remain rejected for the reasons of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford, Ph.D. whose telephone number is 571-272-0757. The examiner can normally be reached on Monday-Saturday, Flex Schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Janet L. Epps-Ford, Ph.D.
Examiner
Art Unit 1635